

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

AVENTIS PHARMA S.A., )  
Plaintiff, )  
v. )  
BAXTER HEALTHCARE CORP., )  
Defendant. )  
C.A. No. 06-636-GMS

## **REPLY TO COUNTERCLAIM**

Plaintiff Aventis Pharma S.A. (“Plaintiff”), for its Reply to the Counterclaim asserted by Defendant Baxter Healthcare Corp. (“Defendant” or “Baxter”), states as follows:

28. Upon information and belief, admits the allegations of ¶ 28 of Defendant's Counterclaim.

29. Admits the allegations of ¶ 29 of Defendant's Counterclaim.

30. Admits that ¶ 30 of Defendant's Counterclaim purports to state a counterclaim under the patent laws of the United States; admits that this Court has subject matter jurisdiction over Defendant's Counterclaim; and denies the remaining allegations of ¶ 30 of Defendant's Counterclaim.

31. Admits that this Court has jurisdiction over Aventis Pharma; and denies the remaining allegations of ¶ 31 of Defendant's Counterclaim.

32. Admits the allegations of ¶ 32 of Defendant's Counterclaim.

33. Admits that Baxter's recombinant Factor VIII product, called ADVATE®, is at issue in this action; and states that Plaintiff is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of ¶ 32 of Defendant's Counterclaim and therefore denies the same.

34. Admits that Exhibit A to Plaintiff's Complaint is a true and correct copy of the '427 patent; denies that Defendant has attached any exhibits to its Answer and Counterclaim; and otherwise admits the allegations of ¶ 34 of Defendant's Counterclaim.

35. Admits the allegations of ¶ 35 of Defendant's Counterclaim.

36. States that Plaintiff is without knowledge or information sufficient to form a belief as to the truth of the allegations of ¶ 36 of Defendant's Counterclaim and therefore denies the same.

37. States that Recombinant Factor VIII may be produced as described in the first two sentences of ¶ 37 of Defendant's Counterclaim; and states that Plaintiff is without knowledge or information sufficient to form a belief as to the truth of the allegations of ¶ 37 of Defendant's Counterclaim and therefore denies the same.

38. Admits that Baxter markets a rFVIII product called ADVATE®; and states that Plaintiff is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of ¶ 38 of Defendant's Counterclaim and therefore denies the same.

39. Upon information and belief, admits the allegations of ¶ 39 of Defendant's Counterclaim.

40. Admits that there is an actual controversy between Baxter and Plaintiff regarding, among other things, Baxter's ADVATE® product, its specific formulation, its method of manufacture, and Baxter's past and ongoing infringement of at least one claim of the '427 patent; and denies the remaining allegations of ¶ 40 of Defendant's Counterclaim.

41. Admits that the first United States application that ultimately led to issuance of the '427 patent was filed by Behringwerke Aktiengesellschaft ("Behringwerke") with the U.S. Patent Office ("USPTO") on or about April 7, 1992; that this application claimed priority to a

foreign application filed in Germany on or about April 9, 1991; that the USPTO notified Behringwerke that the then-pending claims were allowable on or about April 30, 1996; that the '427 patent issued on or about October 15, 1996; that Carol Einaudi, at the time an attorney at Finnegan, Henderson, Farabow, Garrett, & Dunner L.L.P., represented Behringwerke during the original prosecution of the '427 patent; states that Plaintiff is without knowledge or information sufficient to form a belief as to the truth of Defendant's characterization of the term "predecessor-in-interest" and thus denies that Behringwerke is Aventis Pharma's predecessor-in-interest; and denies the remaining allegations of ¶ 41 of Defendant's Counterclaim.

42. Admits that the requirements of 37 C.F.R. §§ 1.56 and 1.555 were satisfied during the prosecution of the '427 patent before the U.S. Patent and Trademark Office; states that the patent statute and 37 C.F.R. §§ 1.56 and 1.555 speak for themselves; states that Plaintiff is without knowledge or information sufficient to form a belief as to the truth of Defendant's characterization of the term "predecessor-in-interest" and thus denies the same; and denies ¶ 42 of Defendant's Counterclaim to the extent it encompasses any further allegations.

43. Denies the allegations of ¶ 43 of Defendant's Counterclaim.

44. Denies the allegations of ¶ 44 of Defendant's Counterclaim.

45. Admits that the U.S. application leading to the '427 patent was pending before the USPTO during some portion of the time period that a European patent application ("EP application") that was filed on or about March 21, 1992 was pending before the European Patent Office; the EP application also claimed priority to the German application; the claims initially filed in the applications submitted to both the USPTO and the European Patent Office were the same; states that Plaintiff is without knowledge or information sufficient to form a belief as to the truth of Defendant's characterization of the term "predecessor-in-interest" and thus denies

that Behringwerke is Aventis Pharma's predecessor-in-interest; and denies the remaining allegations of ¶ 45 of Defendant's Counterclaim.

46. Admits that, during examination of the EP application, a Search Report was generated; states that the 1992 Search Report speaks for itself; and denies the remaining allegations of ¶ 46 of Defendant's Counterclaim.

47. Admits that the European Patent Office sent Behringwerke, in May of 1992, a Search Report; states that the Search Report and listed references speak for themselves; states that Plaintiff is without knowledge or information sufficient to form a belief as to the truth of Defendant's characterization of the term "predecessor-in-interest" and thus denies that Behringwerke is Aventis Pharma's predecessor-in-interest; and denies the remaining allegations of ¶ 47 of Defendant's Counterclaim.

48. Admits that the European Patent Office issued a Communication on or about June 26, 1995; states that the Communication speaks for itself; and denies the remaining allegations of ¶ 48 of Defendant's Counterclaim.

49. Admits that the European Patent Office issued a Communication on or about June 26, 1995; states that the Communication speaks for itself; and denies the remaining allegations of ¶ 49 of Defendant's Counterclaim.

50. Admits that Behringwerke submitted a Communication on or about January 2, 1996; states that the Communication speaks for itself; states that Plaintiff is without knowledge or information sufficient to form a belief as to the truth of Defendant's characterization of the term "predecessor-in-interest" and thus denies that Behringwerke is Aventis Pharma's predecessor-in-interest; and denies the remaining allegations of ¶ 50 of Defendant's Counterclaim.

51. Admits that Behringwerke submitted a Communication on or about January 2, 1996; states that the Communication speaks for itself; states that Plaintiff is without knowledge or information sufficient to form a belief as to the truth of Defendant's characterization of the term "predecessor-in-interest" and thus denies that Behringwerke is Aventis Pharma's predecessor-in-interest; and denies the remaining allegations of ¶ 51 of Defendant's Counterclaim.

52. Admits that the European Patent Office published the patent grant on or about December 10, 1997; states that the patent claims speak for themselves; and denies the remaining allegations of ¶ 52 of Defendant's Counterclaim.

53. States that references cited by the European Patent Office were provided to the USPTO during a reexamination of the '427 patent; states that Plaintiff is without knowledge or information sufficient to form a belief as to the truth of Defendant's characterization of the term "predecessor-in-interest" and thus denies the same; and denies the remaining allegations of ¶ 53 of Defendant's Counterclaim.

54. Admits that amendments were filed with the USPTO on or about September 9, 1993, December 13, 1994, August 24, 1995, and February 29, 1996; states that Plaintiff is without knowledge or information sufficient to form a belief as to the truth of Defendant's characterization of the term "predecessor-in-interest" and thus denies the same; and denies the remaining allegations of ¶ 54 of Defendant's Counterclaim.

55. Admits that amendments were filed with the USPTO on or about August 24, 1995 and February 29, 1996; states that Plaintiff is without knowledge or information sufficient to form a belief as to the truth of Defendant's characterization of the term "predecessor-in-interest"

and thus denies the same; and denies the remaining allegations of ¶ 55 of Defendant's Counterclaim.

56. Admits that Aventis Behring GmbH filed a Request for Reexamination of the '427 patent in the USPTO on or about May 30, 2001; that Carol Einaudi and Sanya Sukduang of Finnegan represented Aventis Behring GmbH during the reexamination of the '427 patent; states that Plaintiff is without knowledge or information sufficient to form a belief as to the truth of Defendant's characterization of the term "predecessor-in-interest" and thus denies that Aventis Behring GmbH is Aventis Pharma's predecessor-in-interest; and denies the remaining allegations of ¶ 56 of Defendant's Counterclaim.

57. Admits that the references cited by the European Patent Office, as well as additional references, were included in Aventis Behring GmbH's Request for Reexamination; admits that the USPTO granted the Request for Reexamination; states that the Request and the USPTO's grant of that Request speak for themselves; states that Plaintiff is without knowledge or information sufficient to form a belief as to the truth of Defendant's characterization of the term "predecessor-in-interest" and thus denies that Aventis Behring GmbH is Aventis Pharma's predecessor-in-interest; and denies the remaining allegations of ¶ 57 of Defendant's Counterclaim.

58. States that the Request for Reexamination speaks for itself; states that Plaintiff is without knowledge or information sufficient to form a belief as to the truth of Defendant's characterization of the term "predecessor-in-interest" and thus denies the same; and denies the remaining allegations of ¶ 58 of Defendant's Counterclaim.

59. Admits that Aventis Behring GmbH submitted to the USPTO references cited by the European Patent Office in the EP application; states that Plaintiff is without knowledge or

information sufficient to form a belief as to the truth of Defendant's characterization of the term "predecessor-in-interest" and thus denies that Aventis Behring GmbH is Aventis Pharma's predecessor-in-interest; and denies the remaining allegations of ¶ 59 of Defendant's Counterclaim.

60. Admits that Aventis Behring GmbH submitted Communications to the USPTO during the Reexamination of the '427 patent; states that those communications speak for themselves; states that Plaintiff is without knowledge or information sufficient to form a belief as to the truth of Defendant's characterization of the term "predecessor-in-interest" and thus denies that Aventis Behring GmbH is Aventis Pharma's predecessor-in-interest; and denies the remaining allegations of ¶ 60 of Defendant's Counterclaim.

61. Denies the allegations of ¶ 61 of Defendant's Counterclaim.
62. Denies the allegations of ¶ 62 of Defendant's Counterclaim.
63. Denies the allegations of ¶ 63 of Defendant's Counterclaim.
64. Denies the allegations of ¶ 64 of Defendant's Counterclaim.
65. Admits that a U.S. Examiner issued an Office Action, citing U.S. Patent No. 4,495,175 ("Chavin") and U.S. Patent No. 4,446,134 ("Naito"); states that the Office Action speaks for itself; states that Chavin and Naito speak for themselves; and denies the remaining allegations of ¶ 65 of Defendant's Counterclaim.

66. Admits that Aventis Berhing GmbH submitted a declaration of Dr. Albrecht Gröner; states that the Gröner declaration speaks for itself; states that Plaintiff is without knowledge or information sufficient to form a belief as to the truth of Defendant's characterization of the term "predecessor-in-interest" and thus denies that Aventis Behring

GmbH is Aventis Pharma's predecessor-in-interest; and denies the remaining allegations of ¶ 66 of Defendant's Counterclaim.

67. Admits that A. Nattermann & Cie GmbH ("Nattermann") filed a Second Request for Reexamination on or about October 21, 2003; that the USPTO granted this Request on or about December 22, 2003; that Carol Einaudi and Sanya Sukduang represented Nattermann during the Second Reexamination of the '427 patent; states that Plaintiff is without knowledge or information sufficient to form a belief as to the truth of Defendant's characterization of the term "predecessor-in-interest" and thus denies that Nattermann is Aventis Pharma's predecessor-in-interest; and denies the remaining allegations of ¶ 67 of Defendant's Counterclaim.

68. Admits that Nattermann submitted Communications to the USPTO during the Second Reexamination of the '427 patent; states that those Communications speak for themselves; states that Plaintiff is without knowledge or information sufficient to form a belief as to the truth of Defendant's characterization of the term "predecessor-in-interest" and thus denies that Nattermann is Aventis Pharma's predecessor-in-interest; and denies the remaining allegations of ¶ 68 of Defendant's Counterclaim.

69. Denies the allegations of ¶ 69 of Defendant's Counterclaim.

70. Denies the allegations of ¶ 70 of Defendant's Counterclaim.

71. Admits that the application leading to U.S. Patent No. 4,758,657 ("Farb") was assigned to Armour Pharmaceutical Company ("Armour") prior to issuance; that the Farb patent was granted on or about July 19, 1988; that on or about February 22, 1995, Armour and Behringwerke, among others, formed a worldwide joint venture, which included Centeon Pharma GmbH ("Centeon"); that on or about December 15, 1999, Rhone-Poulenc S.A.

(Armour's parent company) and Hoechst Aktiengesellschaft (Behringwerke's parent company) merged to form Aventis S.A. and subsequently Centeon Pharma GmbH became Aventis Behring GmbH; and denies the remaining allegations of ¶ 71 of Defendant's Counterclaim.

72. States that Nattermann and Aventis Behring LLC filed suit against Baxter on April 11, 2003 and that the parties to that action stipulated to a dismissal without prejudice of that action; that Nattermann filed an *ex parte* Request for a Second Reexamination of the '427 patent on or about October 21, 2003; that the Farb patent was provided to the USPTO during the Second Reexamination of the '427 patent; that Nattermann filed a request to add claims 14-22 during the Second Reexamination of the '427 patent; states that Plaintiff is without knowledge or information sufficient to form a belief as to the truth of Defendant's characterization of the term "predecessor-in-interest" and thus denies that Aventis Behring or Nattermann is Aventis Pharma's predecessor-in-interest; and denies the remaining allegations of ¶ 72 of Defendant's Counterclaim.

73. Admits that Nattermann submitted the Farb patent during the Second Reexamination of the '427 patent; states that Plaintiff is without knowledge or information sufficient to form a belief as to the truth of Defendant's characterization of the term "predecessor-in-interest" and thus denies that Nattermann is Aventis Pharma's predecessor-in-interest; and denies the remaining allegations of ¶ 73 of Defendant's Counterclaim.

74. Admits that the USPTO granted Nattermann's Request for a Second Reexamination of the '427 patent; states that the grant of the Request speaks for itself; states that Plaintiff is without knowledge or information sufficient to form a belief as to the truth of Defendant's characterization of the term "predecessor-in-interest" and thus denies that

Nattermann is Aventis Pharma's predecessor-in-interest; and denies the remaining allegations of ¶ 74 of Defendant's Counterclaim.

75. Admits that the USPTO issued an Office Action in the Second Reexamination of the '427 patent on or about June 1, 2004; states that the Office Action speaks for itself; and denies the remaining allegations of ¶ 75 of Defendant's Counterclaim.

76. Admits that the USPTO issued an Office Action in the Second Reexamination of the '427 patent on or about December 21, 2004; that the USPTO issued a Reexamination Certificate on or about October 10, 2006; states that the Office Action and Reexamination Certificate speak for themselves; states that Plaintiff is without knowledge or information sufficient to form a belief as to the truth of Defendant's characterization of the term "predecessor-in-interest" and thus denies the same; and denies the remaining allegations of ¶ 76 of Defendant's Counterclaim.

77. Denies the allegations of ¶ 77 of Defendant's Counterclaim.

78. Denies the allegations of ¶ 78 of Defendant's Counterclaim.

79. Denies the allegations of ¶ 79 of Defendant's Counterclaim.

80. Admits that Nattermann submitted Communications to the USPTO during the Second Reexamination of the '427 patent; states that those Communications speak for themselves; states that U.S. Patent No. 6,649,386 ("Roser Patent") speaks for itself; states that the '427 patent claims speak for themselves; states that Plaintiff is without knowledge or information sufficient to form a belief as to the truth of Defendant's characterization of the term "predecessor-in-interest" and thus denies that Nattermann is Aventis Pharma's predecessor-in-interest; and denies the remaining allegations of ¶ 80 of Defendant's Counterclaim.

81. Denies the allegations of ¶ 81 of Defendant's Counterclaim.

82. Admits that there is an actual and justiciable controversy between Plaintiff and Defendant, that Baxter seeks a judicial determination that it does not infringe any valid and enforceable claim of the '427 patent; and that Baxter contests the validity of the claims of the '427 patent and the enforceability of the '427 patent; and denies ¶ 82 of Defendant's Counterclaim to the extent it encompasses any further allegations.

83. Plaintiff incorporates herein by reference its responses to Paragraphs 1 though 82 of Defendant's Counterclaim.

84. Admits that an actual controversy has arisen and now exists between the parties with respect to Baxter's infringement of the claims of the '427 patent, as shown by oral and written communications with Baxter, the first Complaint filed April 11, 2003, and the present Complaint filed October 16, 2006; that Aventis Pharma contends Baxter infringes at least one claim of the '427 patent; that Baxter contends it does not infringe any valid and enforceable claim of the '427 patent; and denies ¶ 84 of Defendant's Counterclaim to the extent it encompasses any further allegations or requested relief.

85. Admits that, pursuant to 28 U.S.C. §§ 2201 and 2202, a judicial determination of the respective rights of the parties with respect to Baxter's infringement of the '427 patent is necessary and appropriate under the circumstances, and denies ¶ 85 of Defendant's Counterclaim to the extent it encompasses any further allegations or requested relief.

86. Plaintiff incorporates herein by reference its responses to Paragraphs 1 though 85 of Defendant's Counterclaim.

87. Admits that Baxter contests the validity of the claims of the '427 patent; and denies ¶ 87 of Defendant's Counterclaim to the extent it encompasses any further allegations or requested relief.

88. Admits that Baxter seeks, pursuant to 28 U.S.C. §§ 2201 and 2202, a judicial determination regarding the validity of the claims of the '427 patent, and denies ¶ 88 of Defendant's Counterclaim to the extent it encompasses any further allegations or requested relief.

89. Plaintiff incorporates herein by reference its responses to Paragraphs 1 though 88 of Defendant's Counterclaim.

90. Admits that Baxter contests the enforceability of the '427 patent and denies ¶ 90 of Defendant's Counterclaim to the extent it encompasses any further allegations or requested relief.

91. Admits that Baxter seeks, pursuant to 28 U.S.C. §§ 2201 and 2202, a judicial determination regarding the enforceability of the '427 patent, and denies ¶ 91 of Defendant's Counterclaim to the extent it encompasses any further allegations or requested relief.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff respectfully requests that the Court deny the relief requested by Defendant, enter judgment in Plaintiff's favor, and grant the relief requested in the Complaint.

ASHBY & GEDDES

*/s/ Lauren E. Maguire*

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